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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,085	05/11/2001	Akihiro Ishii	3007/49966	5264

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EXAMINER

ZUCKER, PAUL A

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

09/853,085

Applicant(s)

ISHII ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13, 25-26 and 28-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4,29 is/are allowed.
- 6) ☒ Claim(s) 2,3,5-13,25,26,28 and 30-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 June 2003 has been entered.

### ***Current Status***

2. This action is responsive to Applicants' amendment of 13 June 2003 in Paper No 15.
3. Receipt and entry of Applicants' amendment is acknowledged.
4. Applicant's cancellation of claim 27 is acknowledged.
5. Applicant's addition of new claims 29-43 is acknowledged.
6. Claims 1-13, 25-26 and 28-43 are currently pending.
7. The rejection under 35 USC §103 (a) set forth in paragraph 7 of the previous Office Action in Paper No 13 is withdrawn upon further consideration by the Examiner. The reasons for this withdrawal are set forth below under the section heading "Allowable Subject Matter".
8. Claims 10, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hagitani et al (JP 09-278718 10-1997).

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The instantly claimed invention is a method for the purification of optically active fluoro- and trifluoromethyl- substituted phenethylamines by formation of the corresponding mandelic or tartaric acid salt followed by recrystallization.

Hagitani teaches (Machine translation, page 5, lines 1-10) a method of purification of disubstituted phenethylamines which proceeds through formation and recrystallization of the mandelic acid salt. Hagitani further teaches (Machine translation, page 3, lines 30-33) disubstituted phenethylamines in which the substituents can be halo (fluoro) and fluoroalkyl (trifluoromethyl). Hagitani specifically teaches (Machine translation, page 3, line 42) 3-fluorophenyl substitution. Hagitani exemplifies (Machine translation, page 14, paragraph [0033]) the process with 3-trifluoromethylphenyl substitution.

Thus the instantly claimed process would have obvious to one of ordinary skill in the art. The motivation would have been to apply the method for purification of disubstituted phenethylamines taught by Hagitani to the purification commercially important compounds. There would have been a reasonable expectation for success since Hagitani teaches that the instant compounds are within the scope of his invention.

***Examiner's Response to Applicants' Arguments with Regard to This Rejection***

9. Applicants have presented several arguments with regard to this rejection. The Examiner responds to these below:

- a. Applicants argue that substitution with trifluoromethyl is not specifically recited. This is incorrect. Hagitani specifically exemplifies (Machine translation, page 14, paragraph [0033]) the process with 3-trifluoromethylphenyl substitution. Hagitani further suggests (Machine translation, page 3, paragraph [0005]) that  $R^1$  and  $R^2$  in the generic formula may be the same. These combined teachings place the claimed method for the purification of 1-(3,5-bis-trifluoromethylphenyl)ethylamine squarely within the scope of Hagitani's teachings.
- b. Applicants further argue that the phenylethylamine taught by Hagitani is not limited to disubstitution but may be unsubstituted or monosubstituted as well. Applicants argue that, therefore, one of ordinary skill in the art would need more guidance to select the compounds from the broad genus taught by Hagitani. The Examiner disagrees. The broad genus of compounds for which Hagitani teaches the method is appropriate speaks more to the expectation for success that one of ordinary skill in the art would have had in applying the method of Hagitani to the instant compound. Based upon the considerations discussed in a. above the Examiner considers Hagitani to provide sufficient guidance for the selection of the instant compound.

Applicant's arguments filed 13 June 2003 have been fully considered but they are not persuasive for the reasons indicated above.

***New Rejections***

***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 2, 3, 5-7, 25-28 and 30-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2,3,5-7, 25-28 and 30-43 recite the limitation "The production process" in line 1. There is insufficient antecedent basis for this limitation in the claim. The Examiner suggests deleting the word "production" in each of the enumerated claims.

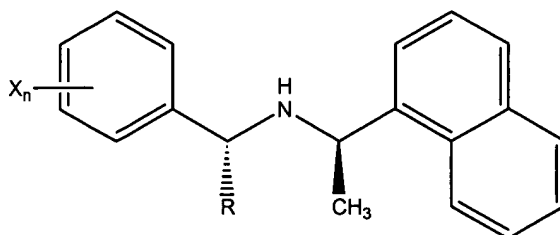
***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 8-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Wagenen et al (US 6,211,244-B1 04-2001).

A method of purification of the 2° amine of formula [4] that comprises formation of an inorganic or organic salt followed by crystallization of the salt is claimed.

Van Wagenen teaches (Column 14, line 50 – column 15, line 12) a genus of compounds that have the structure of instant general formula [4]. Van Wagenen, teaches (Column 13, lines 11-25) a preferred embodiment of the following structure:



where  $n = 1-5$ ;  $X$  may be  $F$  or  $CF_3$ ; and  $R = H$  or  $CH_3$ . Where  $R = CH_3$  this structure then corresponds to the reduced Schiff's base intermediates of the instant claimed process. Van Wagenen further teaches (Column 32, lines 20-38) that compounds of the general structure taught can be converted to the hydrochloride salt and recrystallized as a method of purification. The crystallization of a racemate is deemed by the Examiner to meet the limitations of instant claim 12 since there is no requirement for optical activity.

The motivation would have been to extend the utility of the process for purification of calcium receptor-active compounds taught by Van Wagenen to other, unexemplified, compounds included in the genus taught by Van Wagenen. There would have been a reasonable expectation for success since Van Wagenen teaches the suitability of the crystallization process for compounds belonging to the genus. Thus the instantly claimed invention would have been obvious to one of ordinary skill in the art.

### ***Allowable Subject Matter***

12. Claims 1-7, 25-26 and 28-43 are drawn to allowable subject matter. The following is a statement of reasons for the indication of allowable subject matter: The instantly claimed process for the production of a 1-(fluoro- or trifluoromethyl- substituted) ethylamine is neither disclosed nor fairly suggested by the closest prior art of record,

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Bringman et al (DE 3819438-A1 01-1989) and Van Wagenen et al (US 6,211,244-B1 04-2001). Upon further reconsideration the Examiner finds that there is no motivation for one of ordinary skill in the art to substitute the two step ( a. hydride reduction; b. hydrogenation) process required by the combination of Bringman and Van Wagenen for the single hydrogenation step taught by Bringman alone. Neither of the cited references provides a reason why one of ordinary skill in the art would be motivated to add an additional step to accomplish the same overall process. The instantly claimed process is therefore patentable over the teachings of Bringman and Van Wagenen.

### ***Conclusion***

13. Claims 1-13, 25-26 and 28-43 are currently pending. Claims 2, 3, 5-13, 25, 26, 28 and 30-43 are rejected. Claims 1, 4 and 29 are allowed.

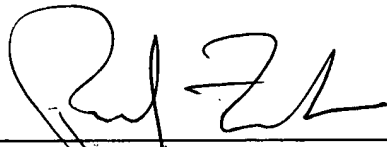
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 703-308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'Paul Zucker', written over a horizontal line.

Paul A. Zucker  
Patent Examiner  
Technology Center 1600